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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,154	09/25/2000	Kaare M. Gautvik	016777/0433	2686

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FOLEY & LARDNER
3000 K Street NW
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Washington, DC 20007

EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/668,154	GAUTVIK ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to paper filed May 3, 2004.

Claims 21 and 22 are under consideration.

Rejections Withdrawn

Double Patenting

The rejection of claim 21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6- 8, and 11 of U.S.

Patent No. 6146852 is withdrawn.

Applicant has filed a terminal disclaimer.

Rejections Withdrawn

The rejection of claims 21 and 22 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Applicants arguments are persuasive.

The rejection of claims 21 and 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Applicant's arguments are persuasive.

Double Patenting

Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6- 8, and 11 of U.S. Patent No. 6146852.

Applicant has filed a terminal disclaimer.

Rejections Maintained

Double Patenting

Claim 21 and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33- 35 of copending Application No. 08/340,664. The earlier claims are drawn to a product by process that requires the same method as the instant claim of a method comprising a yeast or E. coli microorganism that expresses exogenous HPTH (1- 84) and is then purified. It would be obvious to use the method of the product by process as a method to make hPTH (1- 84). Both products have the same structure and both are purified so it would be expected that both would have the same physical properties.

This is a provisional obviousness-type double patenting rejection is maintained until one set of claims is patented.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh *et al.* and Keutmann *et al.*

Keutmann *et al.* teach the sequence for human parathyroid hormone, disclose that it is only available in limited quantities from natural sources and indicate that a supply would be useful for further study.

Keutmann *et al.* does not teach protein expression.

Singh *et al.* teach a method of producing secreted proteins in yeast and that the method results in expression of intact biologically active products with the complete sequence (abstract).

One of ordinary skill in the art at the time of invention would have been motivated to make PTH recombinantly to obtain a supply for further study. One of ordinary skill in the art at the time of invention would have been motivated to use the expression method of Singh *et al.* because secreted proteins are easier to purify than non-secreted and the method makes intact proteins that are biologically active. It would have been

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obvious as well to produce the product in *E. coli* because expression systems were known at the time of invention.

Thus, it would have been *prima facie* obvious to produce purified recombinant intact hPTH using the method of Singh *et al.* to make the product of Keutmann *et al.* with the expectation of success of producing a recombinant intact hPTH(1- 84).


Conclusion

The claim is not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Myron G. Hill
Patent Examiner

~~October 29, 2003~~

6 Aug 04


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
8/9/04